

IAGPA-F-SD

13 December 1983

MEMORANDUM FOR RECORD

SUBJECT: CENTER LANE "HUMAN USE" Procedures (U)

1. (U) References.

a. Procedure 13, DoD Directive 5240.1R (U), dtd Dec 1982 (Incl 1)

b. DAMI-ISH Memorandum, dtd 12 Aug 1983, Subject: CENTER LANE (U)--ACTION MEMORANDUM (S) (Incl 2)

c. 45 CFR 46, "Protection of Human Subjects," (U) dtd 8 March 1983 (Incl 3)

d. (U) USAINS COM Regulation 15-3, "Boards, Commissions and Committees: HIGH PERFORMANCE REVIEW PROCEDURES".

e. (3) (U) AR 381-10, paragraph 2-18 .

f. CENTER LANE Participant Consent Form (S) (Incl 4)

2. (U) The "Human Use" regulations are intended to safeguard subjects from unwittingly risking or incurring adverse effects from scientific experiments in which they are participating. These regulations are based on Public Law 93-348, as interpreted in ref. c. above by the Department of Health and Human Services (DHHS), the proponent agency. By definition, both the Public Law and ref c. apply only to those agencies or contractors receiving grants or other funding from DHHS or its subordinate agencies.

CLASSIFIED BY: CG, INSCOM
DECL: OADR

ARMY review(s) completed.

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3. (S/CL-1/NOFORN) In a memorandum dated 28 October 1981, the technology utilized by USAINS COM's Project CENTER LANE and its predecessor, the Army version of GRILL FLAME, was determined to constitute "human experimentation" by the Army General Counsel, and has since been conducted under the requirements of the "Human Use" regulations governing programs involving experimentation on human subjects (references a, b, and c). With the original GRILL FLAME "Human Use" approval of 1 February 1982 as precedent, the Secretary of the Army most recently authorized the Project to continue under the provisions of said regulations on 1 Sep 1983. Guidelines referenced in paragraph 1. above are made to apply to the CENTER LANE Project through the auspices of ref a., which stipulates that "Experimentation on human subjects...may be undertaken only with the informed consent of the subject, in accordance with" the DHHS guidelines. CENTER LANE activities generally involve well established and thoroughly scientifically validated operational procedures. However, since the Project's mission included the additional requirement to research "emerging technologies," some aspects might by definition have constituted "experimentation on human subjects," and therefore fall under the various guidelines.

4. (S/CL-1/NOFORN) Applying DHHS guidelines to CENTER LANE primarily involved the adoption of procedures insuring that "Informed Consent" was properly obtained from each program participant. Section 46.116, ref c., lists the eight basic elements of "Informed Consent." Of particular importance is subparagraph (a)(1) of Section 46.116, ref c., which requires: "A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental." All personnel directly involved in CENTER LANE operations were required to complete a "Human Use" consent statement (ref f.).

5. (U) Further provisions of the human use regulations, referenced above, require an agency-internal review board to insure compliance with Human Use guidelines. Operating originally as an ACSI-directed project under the GRILL FLAME Protocol of 1 June 1981, Center Lane had heretofore been reviewed by the Department of the Army's general "Human Use" review board. However, on 11 January, 1984 the INSCOM Human Technology Review Board was formed, with the intent of fulfilling review functions IAW references b and d. If the DIA program is adjudged human use, some provision for a review board will be required.

6. (S/CL-2/NOFORN) Actions that will need to be taken on behalf of the developing DIA-centered GRILL FLAME psychoenergetics effort to insure against serious human use reprecussions are as follows:

a. (S/CL-1/NOFORN) Obtain a determination from the DoD General Counsel as to whether or not GRILL FLAME will be interpreted as a human use activity and hence be subject to the pertinent controls and regulations.

b. (U) If the DIA GRILL FLAME program is indeed determined to constitute human use, official approval from Secretary or Undersecretary level must be obtained to allow legal operation of the project. Further, if they are not already, the requisite procedures, as outlined in this paper and references a, b, and c, must be implemented.

4 Incl
as

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